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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,222	01/12/2001	John R. Liddicoat	VIA-14	1731

7590 01/15/2003

Pandiscio & Pandiscio  
470 Totten Pond Road  
Waltham, MA 02451-1914

EXAMINER

GILPIN, CRYSTAL M

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant N .

09/760,222

Applicant(s)

LIDDICOAT ET AL.

Examiner

Crystal M Gilpin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of claims 1-17 and 28 in Paper No. 8 is acknowledged.

Claims 18-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 8.

### *Claim Rejections - 35 USC § 102*

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1-8, 10-13, and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabbay (USPN 6,368,348).

Regarding claims 1-3, Gabbay teaches of an annuloplasty prosthesis or band that is comprised of a ring of graft tissue (Figure 1), wherein the graft tissue may comprise pericardium or other autologous tissue (Column 1, Lines 44-54).

Regarding claims 4 and 14, Gabbay teaches of an implantation flange, or support structure (Figure 6, Ref. Num. 108) that is attached to the annuloplasty band.

Regarding claim 5, Gabbay teaches of a stiffening element or support structure that is internal to the graft tissue (Figures 8 and 9, Ref. Num. 122 and Column 6, Lines 19-47).

Regarding claim 6, 7, 8 and 10-13, Gabbay teaches of an embodiment where the axial structure which the graft tissue is rolled around (Figures 10A and 10B) has two opposing ends and a section between the ends that may be made of a flexible material including suture, plastic or metal (Column 6, Lines 20-25 and 51-65). The ends are adapted to connect to one another once the structure is rolled (Column 7, lines 20-24).

Regarding claim 15 and 16, Gabbay teaches that the prosthesis has an outer sheath which forms a mesh around the graft material and has an extending part that serves as the implantation flange or support structure for suturing to the annulus of the patient (Column 4, lines 49-61 and Column 5, Lines 17-24).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (USPN 6,368,348).

Regarding claim 9, Gabbay teaches that the axial structure is made of a flexible material (Column 6) and that elastic materials may be used for the invention (Column 3, lines 20-32), but he lacks the teaching that the opposing ends of the axial structure are flexible. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Gabbay to have flexible ends on the axial structure to help maintain the original shape of the annuloplasty ring.

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (USPN 6,368,348) in view of Sherman et al. (USPN 5,891,159).

Regarding claim 17, Gabbay teaches the use of purse strings however he does not specify the use of purse string sutures. Sherman et al. teach of a purse string suture device and further teach that the purse string suture is commonly used in cardiac surgery to secure tissue around a cannula (Column 1, Lines 13-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Gabbay to use purse string sutures to securely attach the prosthesis to the annulus.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (USPN 6,368,348) in view of Loch et al. (USPN).

Regarding claim 28, Gabbay does not teach of applying an adhesive to the graft tissue. Loch et al. teach of an annuloplasty ring where an adhesive is applied to the ring material to prevent fraying of the annuloplasty ring material (Column 3, Lines 39-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Gabbay to apply an adhesive or sealant to the graft tissue of the ring to prevent fraying of the ends of the graft tissue.

### ***Conclusion***

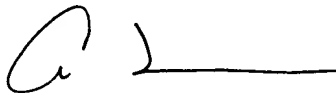
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg  
January 10, 2003



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700